

Food and Drug Administration, HHS

§ 866.1

- 866.5340 Ferritin immunological test system.
- 866.5350 Fibrinopeptide A immunological test system.
- 866.5360 Cohn fraction IV immunological test system.
- 866.5370 Cohn fraction V immunological test system.
- 866.5380 Free secretory component immunological test system.
- 866.5400 *Alpha*-globulin immunological test system.
- 866.5420 *Alpha*-1-glycoproteins immunological test system.
- 866.5425 *Alpha*-2-glycoproteins immunological test system.
- 866.5430 *Beta*-2-glycoprotein I immunological test system.
- 866.5440 *Beta*-2-glycoprotein III immunological test system.
- 866.5460 Haptoglobin immunological test system.
- 866.5470 Hemoglobin immunological test system.
- 866.5490 Hemopexin immunological test system.
- 866.5500 Hypersensitivity pneumonitis immunological test system.
- 866.5510 Immunoglobulins A, G, M, D, and E immunological test system.
- 866.5520 Immunoglobulin G (Fab fragment specific) immunological test system.
- 866.5530 Immunoglobulin G (Fc fragment specific) immunological test system.
- 866.5540 Immunoglobulin G (Fd fragment specific) immunological test system.
- 866.5550 Immunoglobulin (light chain specific) immunological test system.
- 866.5560 Lactic dehydrogenase immunological test system.
- 866.5570 Lactoferrin immunological test system.
- 866.5580 *Alpha*-1-lipoprotein immunological test system.
- 866.5590 Lipoprotein X immunological test system.
- 866.5600 Low-density lipoprotein immunological test system.
- 866.5620 *Alpha*-2-macroglobulin immunological test system.
- 866.5630 *Beta*-2-microglobulin immunological test system.
- 866.5640 Infectious mononucleosis immunological test system.
- 866.5660 Multiple autoantibodies immunological test system.
- 866.5680 Myoglobin immunological test system.
- 866.5700 Whole human plasma or serum immunological test system.
- 866.5715 Plasminogen immunological test system.
- 866.5735 Prothrombin immunological test system.
- 866.5750 Radioallergosorbent (RAST) immunological test system.
- 866.5765 Retinol-binding protein immunological test system.
- 866.5775 Rheumatoid factor immunological test system.
- 866.5785 Anti-Saccharomyces cerevisiae (S. cerevisiae) antibody (ASCA) test systems.
- 866.5800 Seminal fluid (sperm) immunological test system.
- 866.5820 Systemic lupus erythematosus immunological test system.
- 866.5860 Total spinal fluid immunological test system.
- 866.5870 Thyroid autoantibody immunological test system.
- 866.5880 Transferrin immunological test system.
- 866.5890 Inter-*alpha* trypsin inhibitor immunological test system.

Subpart G—Tumor Associated Antigen Immunological Test Systems

- 866.6010 Tumor associated antigen immunological test system.

AUTHORITY: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

SOURCE: 47 FR 50823, Nov. 9, 1982, unless otherwise noted.

Subpart A—General Provisions

§ 866.1 Scope.

(a) This part sets forth the classification of immunology and microbiology devices intended for human use that are in commercial distribution.

(b) The identification of a device in a regulation in this part is not a precise description of every device that is, or will be, subject to the regulation. A manufacturer who submits a pre-market notification submission for a device under part 807 may not show merely that the device is accurately described by the section title and identification provisions of a regulation in this part, but shall state why the device is substantially equivalent to other devices, as required by § 807.87.

(c) To avoid duplicative listings, an immunology and microbiology device that has two or more types of uses (e.g., used both as a diagnostic device and as a microbiology device) is listed only in one subpart.

(d) References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of title 21, unless otherwise noted.

[52 FR 17733, May 11, 1987]